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Ben Franklin Technology Center of Southeastern Pennsylvania

Emerging Company Investments

Final Project Report

Ecton, Inc.

Project # 96S.2180 R-1 **Project Completion:** Redacted

I. Technical Progress

The technical progress of Ecton during this project has been outstanding. The work presented in the BFTC proposal in [illegible] began about a month later than we anticipated. We added a number of capabilities to our product design and incorporated these into our prototype. Despite these changes and our aggressive original time estimates, we managed to stay within a month or two of our projected ending milestones.

We have designed, developed, built and tested the main subsystems of our imaging product. We have completed our product design and produced both a user interface software prototype and an imaging system prototype. Debugging of the imaging prototype took place in April and May, and we obtained our first two-dimensional images in June. These images are quite good and the company now can state that it has proven the technical feasibility of our design. We now have a great deal of confidence that we can meet our product cost, capability, and timing targets.

Regarding the specifics of the Ben Franklin project relating to contrast imaging we have thoroughly met most of the major milestones described in our proposal. These are grouped below with comments.

Milestones 1- 3

1. Characterize Contrast Agent Detection and Display Parameters and Functions.
2. Specify and Design Front End / Beamformer Modifications
3. Specify Software Algorithms

Early in the project we worked with our collaborators at the University of Pittsburgh to develop an accurate understanding of the system requirements for contrast imaging. The objective was to insure that our product architecture allowed for the imaging acquisition and processing techniques required.

The proposal stated that the most important area of work in the project was the development of a high performance, low cost digital beamformer and front end. Our approach to this problem has a number of unique and proprietary elements and this represented the greatest technical risk, and one of the most promising areas for a distinct technical advantage.

We have now proven that our approach works extremely well. This represents a breakthrough in the industry. Products with digital beamformers cost four times and more what we now project our sales price to be.

The current design incorporates the capabilities we identified for contrast imaging. This includes wide bandwidth operation, ECG triggering for gated image acquisition, dual frequency transmit and receive operation for harmonic mode imaging, frequency agility, and bandwidth optimization.

Milestones 4 - 10

4. Obtain Prototype Parts
5. Begin Prototype Build
6. Begin Software Algorithm Coding
7. Establish Prototype Lab Test Protocol
8. Complete Prototype
9. Complete Prototype / Lab Test Protocol

10. Measure Prototype Against Spec

The prototype parts procurement and assembly started in February and was completed in stages in April and May. The digital portion of the system had been debugged by mid May. The analog portion had been debugged by late May. Images were obtained during the first week of June. The Lab test protocol issue is discussed below.

Milestones 11 - 14

11. Initial In Vitro Testing of Prototype Imaging
12. Off-line Testing of Imaging Processing Techniques
13. Plan for Phase 2 : System Integration
14. Plan for Phase 2 : Human Clinicals

The prototype we have operating now is actually doing human scanning, not just in vitro testing. We have been able to image normal subjects in our lab and compare our image quality to commercially available machines. We have developed a detailed plan for the next phase of product development. Over the next 12 months we expect to add color flow mapping techniques, integrate the system hardware with operating software, develop the mechanical package, and produce a pre-production clinical testing unit.

There are a few areas where we have not yet been able to do some of the tasks described in the project plan. Several of the contrast imaging-specific capabilities that are built into the prototype have not been fully tested and debugged. This includes some of the ECG processing circuitry, and harmonic mode operation. We expect to test these over the next few weeks.

We have also not been able to conduct the in vitro experiments we had anticipated doing with Dr. Cape's laboratory. We are anticipating conducting these over the summer. These are likely to be performed in our own laboratory, with guidance provided by Dr. Cape and Dr. Villanueva.

We have found the relationship with Pitt to be beneficial and important and we expect to continue it using our own funds. We expect to continue to work with them over the summer evaluating the prototype performance. We have been unable to do what we projected regarding the testing of image post processing techniques using our image data but we have been working with Dr. Villanueva on designing test plans for image post processing which in the near future can be applied to our images. Her lab has continued experiments in this area which we are supporting. This is a promising area and we expect to continue working with Dr. Villanueva on this during the summer.

II. Commercialization

Ecton is expecting to have an integrated clinical prototype in approximately one year. This would be in the form of a packaged unit providing imaging capabilities which can be tested on patients in a hospital setting. It is expected that contrast imaging will be a part of this prototype. Once clinical acceptance is achieved, it is anticipated that production and product release can take place within about six months. We anticipate pursuing regulatory approvals so that they are in place around the time of initial clinical testing.

Because we are in a development stage, our commercialization activities are limited. The company has prepared a detailed sales and marketing plan. A summary of the plan is attached. We have also maintained a very active investigation of the clinical applications of our technology, working with a select group of clinical advisors. Developments in this area are quite promising. Over the course of the project period a number of important clinical studies have been published demonstrating the benefits of

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Minutes of Board of Directors Meeting

A meeting of the Ecton, Inc. Board of Directors was held on [redacted] at 10:30 am in the offices of Drinker, Biddle & Reath, in Philadelphia, Pennsylvania. In attendance were Michael Cannon, Michael Keehan, Esq., Christopher Knell, George Magovern, M.D., and Bernard Steinberg,PhD.

The minutes of the [redacted] meeting were adopted as written.

C. Knell provided a report on the engineering and technical developments at the company. As a reference point, a development schedule and overview prepared in [redacted] was presented. In this overview the company projected that its first phase of operations would run from September 1996 through April 1997 and consume approximately [redacted] The outcomes were to be an imaging prototype, package and user interface prototype, detailed design documentation and select patent applications. With the exception of the patent applications, and the fact that the imaging prototype was not fully operational until early June, the goals of Phase were largely met. Patent applications were postponed primarily for financial considerations. This activity will be revived over the next few months.

Back in [redacted]. Phase 2 was projected to require [redacted] last from [redacted] and result in a fully working clinical prototype, complete engineering and manufacturing documentation, and the FDA 510k review. It is now projected that this period will more likely extend to around [redacted] manufacturing-related documentation will be preliminary, and the submittal to the FDA may not be completely readied until the August-September timeframe. Otherwise the projection of accomplishments, major milestones and required funds remains very close to this original schedule.

The need to address the company's longer term plans for product marketing and potential business alliances or acquisition was raised by members of the Board. It was agreed that a Board meeting devoted primarily to this topic was called for and that the better part of a day in December should be scheduled for this purpose.

In early June, the original imaging prototype was made operational and high quality images were produced. Realtime scans in the lab were shown to John Ross, RCVT, of Hahnemann/Allegheny University, and Dr. Liza Villanueva, a cardiologist from the University of Pittsburgh, and their opinions of the image quality was very positive.

[redacted]